GANFORT® (bimatoprost 0.03%/timolol 0.5%). Abbreviated Prescribing Information. Presentation: Eye drop solution, one ml contains 0.3mg bimatoprost and 5mg timolol (as maleate). Indications: Reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. Dosage and Administration: Please refer to the Summary of Product Characteristics before prescribing. Recommended dose is one drop in the affected eye(s) once daily, administered in the morning (evening dosing may be considered). If more than one topical ophthalmic product is to be used, each should be instilled at least 5 minutes apart. Not recommended in children or adolescents (under the age of 18). Use with caution in renal or hepatic impairment. Contraindications: Hypersensitivity to active substances or to any of the excipients. Reactive airway disease including bronchial asthma or a history of bronchial asthma, severe chronic obstructive pulmonary disease. Sinus bradycardia, second or third degree atrioventricular block, overt cardiac failure, cardiogenic shock. Warnings/Precautions: Ganfort may be absorbed systemically. The same types of cardiovascular and pulmonary adverse reactions as seen with systemic beta-blockers may occur. Cardiac failure should be adequately controlled before beginning therapy. Patients with a history of severe cardiac disease should be watched for signs of cardiac failure and have their pulse rates checked. Cardiac and respiratory reactions, including death due to bronchospasm in patients with asthma, and, rarely, death in association with cardiac failures have been reported following administration of timolol maleate. Beta-blockers may also mask the signs of hyperthyroidism and cause worsening of Prinzmetal angina. Adverse reactions as seen with systemic beta-blockers may occur. Cardiac and respiratory failure and have their pulse rates checked. Cardiac and respiratory effects resulting in hypotension, and/or marked bradycardia when eye drops containing timolol are administered concomitantly with oral calcium channel blockers, guanethidine, or beta-blocking agents, anti-arrhythmics, digitalis glycosides or parasympathomimetics. The hypertensive reaction to a variety of allergens may be unresponsive to the usual dose of adrenaline used to treat anaphylactic reactions. In patients with a history of mild liver disease or abnormal alanine aminotransferase (ALT), aspartate aminotransferase (AST) and/or bilirubin at baseline, bimatoprost had no adverse reactions on liver function over 24 months. There are no known adverse reactions of ocular timolol on liver function. Before treatment is initiated, patients should be informed of the possibility of eyelash growth, darkening of the eyelid skin and increased iris pigmentation since these have been observed during treatment with bimatoprost and Ganfort. Some of these changes may be permanent, and may lead to differences in appearance between the eyes if only one eye is treated. After discontinuation of Ganfort, pigmentation of iris may be permanent. After 12 months treatment with Ganfort, the incidence of iris pigmentation was 0.2%. After 12 months treatment with bimatoprost eye drops alone, the incidence was 1.5% and did not increase following 3 years treatment. Cystoid macular oedema has been reported with Ganfort. Therefore, Ganfort should be used with caution in patients with known risk factors for macular oedema (e.g. aphakic patients, pseudophakic patients with a torn posterior lens capsule). The preservative in Ganfort, benzalkonium chloride, may cause eye irritation. Contact lenses must be removed prior to application, with at least a 15-minute wait before reinsertion. Benzalkonium chloride is known to discolour soft contact lenses; avoid contact. Benzalkonium chloride has been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy. Therefore monitoring is required with frequent or prolonged use of Ganfort in dry eye patients or where the cornea is compromised. Ganfort has not been studied in patients with inflammatory ocular conditions, neovascular, inflammatory, angle-closure glaucoma, congenital glaucoma or narrow-angle glaucoma. Potential for additive effects resulting in hypotension, and/or marked bradycardia when eye drops containing timolol are administered concomitantly with oral calcium channel blockers, guanethidine, or beta-blocking agents, anti-arrhythmics, digitalis glycosides or parasympathomimetics. The hypertensive reaction to sudden withdrawal of clonidine can be potentiated when taking beta-blockers. There are no adequate data from the use of Ganfort in pregnant women. Do not use during pregnancy unless clearly necessary. Ganfort should not be used by breast-feeding women. Ganfort has negligible influence on ability to drive and use machines. Adverse Effects: No adverse drug reactions (ADRs) specific for Ganfort have been observed in clinical studies. The ADRs have been limited to those earlier reported for bimatoprost and timolol and the majority were ocular, mild in severity and none were serious. Based on 12-month clinical data, the most commonly reported ADR was conjunctival hyperaemia (mostly trace to mild and thought to be of a non-inflammatory nature) in approximately 26% of patients and led to discontinuation in 1.5% of patients. The following ADRs were reported during clinical trials with Ganfort. Eye disorders: Very common (≥1/10): conjunctival hyperaemia, growth of eyelashes. Common (≥1/100 to <1/10): superficial punctate keratitis, corneal erosion, burning sensation, eye pruritus, stinging sensation in the eye, foreign body sensation, eye dryness, eyelid erythema, eye pain, photophobia, eye discharge, visual disturbance, eyelid pruritus. Skin and subcutaneous tissue disorders: Common: blepharal pigmentation. Additional adverse events that have been seen with one of the components and may potentially occur also with Ganfort. Please refer to Summary of Product Characteristics for full information on side effects. Basic NHS Price: £13.95 per 3ml bottle. £37.59 for 3x3ml bottle. Marketing Authorisation Number: EU/1/06/340/001-002. Marketing Authorisation Holder: Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, Co. Mayo, Ireland. Legal Category: POM. Date of Preparation: March 2009. Further information is available from: Allergan Ltd, Marlow International, The Parkway, Marlow, Bucks, SL7 1YL.


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